



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/566,757

02/01/2006

Bo Wegge Laursen

LAURSENIA

7326

1444 7590 10/05/2011

Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

EXAMINER

SHTERENGARTS, SAMANTHA L

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

10/05/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,757	Applicant(s) LAURSEN ET AL.	
	Examiner Samantha Shterengarts	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-5,9,12,70-74,78,83,85,87,91 and 94-96 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-5,9,12,70-74,78,83,85,87,91 and 94-96 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/17/06, 10/25/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. The instant application is a national stage entry of PCT/DK2004/000518, filed July 30, 2004, which claims priority to U.S. Provisional application no. 60/491,527, filed August 1, 2003.
2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. PA 2003 01121 filed in the Danish Patent Office on 08/01/2003 which papers have been placed of record in the file.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on May 17, 2006 and October 25, 2006 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS documents were considered. A signed copy of each form 1449 is enclosed herewith.

Election/Restrictions

4. Applicant's election with traverse of the elected species in the reply filed on 19 July 2011 is acknowledged. The traversal is on the ground(s) that unity is not lacking in a PCT application and therefore, a restriction is improper. In the instant case, the special technical feature is compounds of claim 1 and the claims are found to lack unity because the special technical feature does not make a contribution over the prior art as evidenced by the anticipation rejections below. Therefore, the restriction requirement is proper. However, upon further consideration, Examiner has withdrawn the restriction requirement and claims 1-5, 9, 12, 70-74, 78, 83, 85, 87, 91, and 94-96 are under consideration.

Status of the Claims

Art Unit: 1626

5. Currently, Claims 1-5, 9, 12, 70-74, 78, 83, 85, 87, 91, and 94-96 are pending in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5, 9, 12, 70-74, 78, 83, 85, 87, 91, and 94-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The claims recite the phrase “comprising the structure” with regard to compounds of claims 1 and 70. Forms of the term "comprising" can be considered open ended language and is therefore including additional subject matter in the compounds of the claims that is not described in the instant specification and is not particularly pointed out or distinctly claimed. A definition of a chemical compound cannot be open-ended, as “comprising” a particular structure because it appears that that structure can be isolated, or can be otherwise embedded in a larger structure “comprising” a smaller structure inside of it. Definitions for chemical compounds should be claimed in precision.

b. Regarding the claims the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). In claim 1, for example, first page where R1-R10 are defined and then on second page of claim 1, middle of page “or where at least one of R1, R2, R3...R10 comprises at least one reactive group or at least one reactive moiety...such as N-succinimidyl ester...such as pentafluorophenol...such as sulfonyl chloride...” It is

Art Unit: 1626

unclear if all activated esters are being claimed, or only N-succinimidyl ester, maleimide ester, or fluorophenol ester, for example.

c. In claim 70, there is no limitation for NR5R6, NR1R2, and NR3R4, the R groups together with the nitrogen form a heterocyclic ring (claims page 2 of 13, page numbered 3, lines 5-11); however, the same proviso where NR3R4 and NR5R6 cannot be morpholinyl appears in claim 70, which would mean that they can form a heterocyclic ring together. For the purposes of applying art, it will be read as though in claim 70, NR5R6, NR1R2, and NR3R4, the R groups together with the nitrogen form a heterocyclic ring.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 9, 12, 70-74, 78, 83, 85, 87, 91, and 94-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite the limitations, “reactive moiety” and “or a precursor thereof” (claims 91 and 94-96) in reference to the instantly claimed compounds and their derivatives. Applicant has not described the claimed genus of “reactive moiety” and “or a precursor thereof” in a manner that would indicate they were in possession of the full scope of this genus, or even to

Art Unit: 1626

describe what this genus is comprised of.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, the claimed "reactive moiety" and "or a precursor thereof" encompass any compound that contains the identical core as the instantly claimed compound, with a differing of substituents quoted for the identical purpose. Applicants describe no "reactive moiety" and "or a precursor thereof" adequately enough to allow one skilled in the art to

Art Unit: 1626

ascertain that Applicant is in possession of the entire scope of that genus. The specification discloses the following: “[0075] The term "derivative of a reactive group" denotes a reactive group (e.g. a reactive group of a substituted alkyl) which has been reacted with a chemical moiety, said reaction generating the derivative by attaching the chemical moiety (optionally the part of the chemical moiety which is not consumed in the reaction with the reactive group) to the fluorescent dye compound. The derivative can be e.g. an activated ester or a monomer or a macromonomer. [0076] The term "reactive moiety" is used interchangeably with "derivative of a reactive group". A substituent of the fluorescent dye compound can comprise a "reactive moiety", or the "reactive moiety" can be attached to the fluorescent dye compound by reaction with a substituent in the form of e.g. a substituted alkyl capable of reacting with the reactive moiety (precursor).”

Applicants have not described this genus of derivatives in a manner that would allow one skilled in the art to immediately envisage the compounds contemplated for use. As such, the claims lack adequate written description for the claimed “reactive moiety” and “or a precursor thereof.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 9, 12, 70-71, 78, 83, 85, and 87 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Laursen et al. [Laursen, Bo W. 2,6,10-

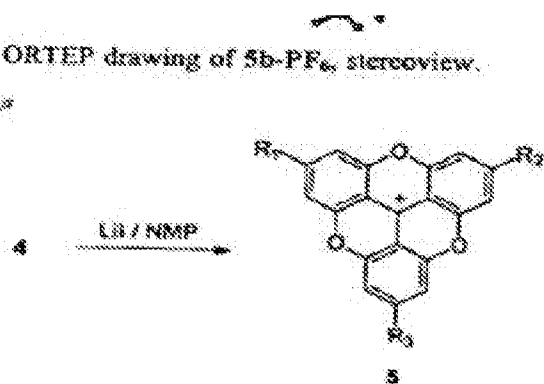
Art Unit: 1626

Tris(dialkylamino)trioxatriangulenium Ions. Synthesis, Structure, and Properties of Exceptionally Stable Carbenium Ions. *J. Am. Chem. Soc.* 120, (1998), 12255-12263.]

Laursen et al. teaches the following anticipatory species:

Figure 2. ORTEP drawing of 5b-PF₆, stereoview.

Scheme 3*



* 5a: R₁ = R₂ = R₃ = NEt₂. 5b: R₁ = R₂ = R₃ = N-pyrrolidinyl.
5c: R₁ = NEt₂, R₂ = R₃ = N-morpholinyl.

wherein Z is O, X1, X3, X5, X7, X9, and X11 are H, Y is NR₅R₆; in NR₅R₆, NR₁R₂, and NR₃R₄, the R groups together with the nitrogen form a heterocyclic ring (claims page 2 of 13, page numbered 3, lines 5-11).

Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626
/Rebecca L Anderson/

Primary Examiner, Art Unit 1626